

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WISCONSIN**

PROMEGA CORPORATION,

Plaintiff,

and

MAX-PLANCK-GESELLSCHAFT zur
FORDERUNG der WISSENSCHAFTEN E.V.,

Case No. 10-cv-281-bbc

Involuntary Plaintiff,

v.

LIFE TECHNOLOGIES CORPORATION,
INVITROGEN IP HOLDINGS, INC., and
APPLIED BIOSYSTEMS, LLC,

Defendants.

**AFFIDAVIT OF MICHELLE SHEPHERD IN SUPPORT OF
DEFENDANTS' BRIEF IN OPPOSITION TO PROMEGA CORPORATION'S
MOTION FOR SUMMARY JUDGMENT**

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1. I, Michelle Shepherd, am the District Manager for Human Identification Support at Life Technologies Corporation ("Life Technologies"), and certify under penalty of perjury that the following is true and correct to the best of my knowledge and recollection.

2. I manage a team of Field Application Specialists (FAS) which supports customers using Life Technologies' AmpFISTR kits. This particular FAS team is composed of four individuals, including myself, and two other technical support personnel. We conduct trainings, develop the curriculum for the trainings, troubleshoot customer issues and inquiries, and manage calls, emails, and inquiries from customers.

3. Approximately 95%-98% of Life Technologies' AmpFISTR kit customers are crime labs and other forensics-based customers. This figure represents my best estimate as the Life Technologies Support team does not actively track customer use of AmpFISTR kits. The FAS team is not aware of exactly how many AmpFISTR kit customers exist because we are typically not contacted by customers unless there is a troubleshooting issue or inquiry which arises on which they need our support.

4. A small fraction of customers are what we internally call "non-HID" customers. "HID" refers to "Human Identity" and is a phrase coined within Life Technologies that has a specific shared internal understanding. The term "non-HID" has come to mean "non-forensic."

5. The FAS team is instructed to support and does support customers according to a validated protocol for the AmpFISTR kits. The validated protocols are forensics-based protocols and were developed according to standards set by the Scientific Working Group on DNA Analysis Methods (SWGDAM), the American Society of Crime Lab Directors (ASCLD-LAB), and the National DNA Index System (NDIS), bodies which are all forensics focused certifying entities. (Life Technologies does not promote the AmpFISTR kits for clinical use because the

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kits were not developed and validated according to the standards set by the FDA, CLIA, AABB, or other clinical bodies.) SWGDAM is a working group composed of scientists who represent federal, state, and local forensic laboratories in the United States and Canada. The NDIS is a database which contains DNA profiles of convicted offenders, arrestees, and other persons contributed by participating federal, state, and local forensic laboratories. There are quality standards that DNA data must meet in order to be accepted in the NDIS. In forensic applications, typically very low quantities of DNA, and often times degraded or contaminated, are gathered and accordingly forensic analyses must be performed using very low sample quantities. In contrast, when a sample of DNA is taken from a bone marrow donor or recipient, for example, large amounts may be extracted under sterile conditions such that the sample is not contaminated and the DNA is not degraded. The validated protocols were developed and optimized for samples usually quanting within picogram to nanogram range of DNA, which reflects a forensics type of analysis. Reagent quantities and other reaction parameters and conditions were optimized to produce reproducible, robust, and reliable data quality for sample types frequently encountered in forensics.

6. Often a customer's application is not known because their question or problem may relate to hardware, software, consumables, or other issues that do not implicate any particular application. In any case, when the FAS team supports its customers, they are instructed to adhere to the validated protocol, regardless of the customer's specific application. For example, the FAS team is instructed to refer to samples as "suspect" and "victim" or "male" and "female" instead of "donor" and "recipient." The FAS team also advises customers of the label license on the AmpFISTR kit packaging, which also appears prolifically throughout the product manuals, publications, website, and presentations. The label specifically states "For

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Research, Forensics, and Paternity Use Only. Not for use in Diagnostic Procedures." Customers may change or depart from the validated protocol once the call or visit with them is over, but the FAS team does not instruct or encourage them to do so.

7. Customers will often depart from the forensics workflow. For example, they may change the polymer from POP-4 to POP-7, which tends to be used in sequencing applications rather than fragment analysis due to its greater viscosity and higher specific gravity. They may contact the FAS team believing that their instrument is malfunctioning and wanting a replacement. To assure the customer that the forensics workflow is in fact a robust system which gives reproducible, robust, and reliable data, and to ensure that Life Technologies does not have to supply expensive replacement instruments and kits to these customers, the FAS team stresses in all trainings and presentations that the AmpFISTR kits are designed to work within a specific forensics workflow and guides the customer back to this workflow. When customers adhere to the forensics workflow, things work as they should and the customers are shown that their instruments, software, and chemistry are in reality all performing well.

8. Sometimes, a single customer will run both AmpFISTR kits and STR kits sold by Promega, rather than one vendor's kit exclusively.

9. Lisa Ortuno was a member of the FAS team which supports the AmpFISTR kits. She gave her notice of voluntary resignation to me on September 2, 2011. She took personal time off between September 10-15, 2011, and her last day of employment at Life Technologies was September 16, 2011. Ms. Ortuno has a background in R&D, whereas the rest of the FAS team which supports AmpFISTR kits has a forensics background. A very general distinction I would make is that people from R&D tend to think creatively and like to problem solve, whereas

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people from forensics are very precise about following protocols to the letter, understanding that their analyses must withstand aggressive scrutiny at a criminal trial.

Dated: September 21, 2011.

Michelle S. Shepherd
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